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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,544	03/30/2004	Stephen D. Pacetti	50623.00376	7422

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

Office Action Summary	Application No. 10/814,544	Applicant(s) PACETTI, STEPHEN D.	
	Examiner Jennifer K. Michener	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 1-18 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-18 of copending Application No. 10/729,551. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-3, 5-12, and 14-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-7, and 9-10 of U.S. Patent No. 6,743,462. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Independent application claim 10 is merely a broader embodiment of the patent's claim 1, both of which require selection of a pressure based on solvent vapor pressure.

Independent application claim 1 requires selection of pressure based on a desired rate of evaporation, which would be based on the volatility of the solvent, which is the basis of pressure selection of the independent claim of the patent. Both use pressure to affect evaporation rate based on the volatility of the solvent.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 9, 10, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frisch (4,992,312).

Frisch teaches a method of forming a coating for an implantable medical device by applying a coating comprising a solvent to the device, whereby evaporation of the solvent may be accelerated by lowering the pressure (abstract; col. 6, line 10; col. 8, line 20), as required by claim 1. The process of lowering the pressure inherently requires the use of a chamber in which the pressure is adjusted to a pressure other than (i.e., lower than) ambient. What Frisch fails to specifically teach is coating the device in the pressure chamber. However, it is Examiner's position that it would have been obvious to one of ordinary skill in the art to coat and dry the device in the same chamber with the expectation of a more efficient process. Since Frisch aims to speed up evaporation and since immediate application of lower pressure during coating in the coating chamber would do so faster than would occur by removing the device to a second chamber, it would have been obvious to one of ordinary skill in the art to coat and pressure-treat the medical device in the same chamber at the same time.

Regarding claim 10, requiring "wherein the pressure is selected based on the vapor pressure of the solvent", Examiner notes that Frisch teaches that decreased pressure increases evaporation rate, indicating that pressure is a cause-effective variable in evaporation rates. In selecting a lowered pressure to achieve Frisch's desired

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evaporation rate, one of ordinary skill in the art must necessarily base the pressure selection on the vapor pressure of the solvent. Selection of a variable, such as pressure, for a coating operation would have been within the skill of an ordinary artisan. Like temperature, pressure is known to affect evaporation and it would have been obvious for an ordinary artisan to optimize pressure to achieve desired results. It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

The applied composition of Frisch includes a polymer (col. 8, line 1).

8. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. (6,358,556) in view of You et al. (6,407,009).

Ding teaches coating implantable stents with a thin layer(s) of a coating composition comprising a solvent mixture of polymer and biologically active species (abstract; col. 3, line 17). The coating of Ding is applied by spraying the composition on a rotating stent, using an evaporative solvent that has a high vapor pressure to produce a desired viscosity and layer thickness (col. 3, lines 48-53).

What Ding fails to teach is coating the stent in an atmosphere having a pressure other than ambient pressure.

You teaches decreasing the evaporation rate of solvent from a spinning substrate by increasing the pressure in a closed chamber during coating in order to provide a thin,

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more uniform coating (abstract, line 2; col. 2, lines 5-8; col. 6, line 41-col. 7, line 8; col. 7, line 39).

Examiner notes that You teaches coating with resist liquids, which comprise a polymer in an evaporative solvent.

Since Ding teaches coating thin layers of polymer solutions onto a rotating substrate and You teaches the use of increased pressure to reduce the evaporation rate of a solvent to form a thin, more uniform polymer layer on a rotating substrate, You would have reasonably suggested the use of his pressure chamber in the method of Ding. It would have been obvious to one of ordinary skill in the art to use the teachings of You in the method of Ding because it would have been expected that the pressurizing method of Ding would have enhanced the uniformity of Ding's coating on a spinning device in the same successful manner as was accomplished in the method of You.

Since You teaches that the use of increased pressures is to counter-balance the volatility of certain solvents which evaporate too rapidly, the pressure of You is selected "based on the vapor pressure of the solvent", as required by claim 10.

As discussed above, Ding teaches a coating composition of polymer and therapeutic agent dissolved in a solvent, as required by claims 2 and 11. Ding generically teaches the use of antibiotics as the biologically active species in the composition of his invention (col. 5, line 2). While Ding does not specifically teach the use of actinomycin D as the bioactive agent, Examiner notes that actinomycin D is an antibiotic agent well-

known in the medical coating art. It would have been obvious to one of ordinary skill in the art to select a specific antibiotic, actinomycin D, as required by claims 3 and 12, from the broad class "antibiotics" taught by Ding because a specific member of the broad class would be expected to function in a similar and successful manner of providing antibiotic properties to a stent.

Ding teaches the use of xylene or THF, among others, as exemplary solvents for use in his method, as required by claims 4 and 13 (examples).

Regarding claims 5, 6, 14, and 15, Ding teaches spraying the expandable stent with the composition while rotating, as outlined above (col. 1, line 25; col. 7, line 57).

In regard to claims 7 and 16, Ding teaches spraying the stent using a sweeping motion of the spray brush from the proximal end to the distal end of the stent (col. 7, line 58-65). Examiner notes that Applicant requires movement of the stent in the longitudinal direction while spraying the stent, while Ding requires movement of the sprayer along the longitudinal direction of the stationary stent. However, linear movement of the stent relative to the sprayer is equivalent in function to linear movement of the sprayer relative to the stent. It would have been obvious to interchange these two types of movement with the expectation of equivalent results in applying a uniform coating to the stent.

Regarding claims 9 and 18, Ding teaches the use of polymer solutions or suspensions, indicating dissolution of the polymer in the solvent in at least some of Ding's embodiments.

Regarding claims 8 and 17, Ding inherently uses a temperature that does not adversely affect the therapeutic agent or else his final product would not be effective in treating the diseases and conditions of his invention.

9. Claims 1-5, 8-14, and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy (6,153,252) in view of You et al.

Hossainy teaches a method of coating stents with a composition comprising a solvent.

Hossainy teaches optimization of the evaporation rate of the solvent to properly coat the stents (col. 6, line 46).

What Hossainy fails to teach is the use of pressure to optimize his evaporation rate.

You et al. teach that which is disclosed above, namely that the evaporation rate of solvent may be decreased by an increase in the pressure, i.e., above ambient, in the closed chamber during coating in order to provide a thin, more uniform coating.

Examiner notes that You teaches coating with a polymer in an evaporative solvent, similar to Hossainy.

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Since Hossainy teaches that evaporation rates of solvents must be controlled to properly coat stents and You teaches the use of increased pressure to reduce, i.e., control, the evaporation rate of a solvent to form a thin, more uniform polymer layer on a substrate, You would have reasonably suggested the use of his pressure chamber in the method of Hossainy to do so. It would have been obvious to one of ordinary skill in the art to use the teachings of You in the method of Hossainy to provide Hossainy with a method of controlling solvent evaporation rates, as he teaches is desirable, to enhance the uniformity of Hossainy's coating.

Since You teaches that the use of increased pressures is to counter-balance the volatility of certain solvents which evaporate too rapidly, the pressure of You is selected "based on the vapor pressure of the solvent", as required by claim 10.

Hossainy teaches spray-coating with a dissolved polymer and therapeutic agent, such as paclitaxel (col. 8, line 60). Hossainy teaches the solvents of Applicant (col. 4-col. 8).

Regarding claims 8 and 17, Hossainy inherently uses a temperature that does not adversely affect the therapeutic agent or else his final product would not be effective in treating the diseases and conditions of his invention.

Conclusion

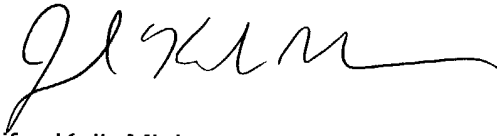
10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Marikar et al. (5,017,420) teaches that the rate at which solvent is evaporated increased with reduced pressure (DET 36). Ekman et al. (4,822,535) teaches that evaporation rate can be increased by heating or reduced pressure (BST 21). Schwarz et al. (6,368,658) teaches the use of a closed Wurster column for coating stents with solvent-based coatings under a pressure of 2-20 psi, wherein evaporation rates would be decreased when above ambient and increased when below ambient. Finsterwalder (20020136903) teaches using low pressure to increase rate of solvent evaporation.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'J. Kolb Michener', with a long horizontal flourish extending to the right.

Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
September 6, 2004